

510 (k) S U M M A R Y

K970370

## TSK STERIEKT Premium Disposable Hypodermic Needle

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**Device Trade Name:** TSK STERIEKT Premium Disposable Hypodermic Needle  
**Common Name:** Hypodermic Needle  
**Classification Name:** Hypodermic Single Lumen Needle (per 21CFR 880.5570)

**Predicate Device:** Becton Dickinson & Company, 'B-D PrecisionGlide' needles

**Description of Device:** TSK STERIEKT is a sterile Hypodermic Single Lumen Needle, packaged individually for single patient use. It consists of a stainless steel beveled cannula bonded to a plastic hub. Sizes include 14G-31G and various lengths. The needle is intended to fit any luer lock or luer slip syringe tip.

**Intended Use:** To inject fluids into, or withdraw fluids from parts of the body below the surface of the skin.

**Safety and Efficacy:** The following tests were performed to show the safety and efficacy of the device.

<u>TEST</u>	<u>RESULT</u>
Protector Removal	Meets Specification
Needle Bond Strength	Meets Specification
Sensitization	Pass
Intracutaneous	Pass
Hemolysis	Pass
Systemic Toxicity	Pass
LAL Pyrogen Test	Pass
Cytotoxicity	Pass

**Substantial Equivalence:** The TSK Premium Disposable Hypodermic Needle and the predicate device, the B-D PrecisionGlide Needle, have been shown to be substantially equivalent based on the following:

- identical intended use - disposable sterile hypodermic needle, individually packaged.
- equivalent materials - stainless steel cannula and plastic hub.
- equivalent design - metal cannula with bonded plastic hub; removable plastic protector on needle tip; sufficient physical integrity for the intended use; fits Luer Lock or Luer Slip hypodermic tips.
- similar size range - TSK 14G-31G; B-D 16G-30G.
- needle tip selection - both brands are available with several bevels.